Released permission for finished medicines

1891. DR. (SHRIMATI) SAROJINI MAHISHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what are the requirements to be fulfilled for obtaining the permission of Control release finished medicines;

(b) the names of medicines for which Government granted control release permission during last two years along with the details of trials, study, tests conducted on each of them;

(c) what are the names of centres and laboratories where such studies and trials were conducted;

(d) whether it is a fact that State Drug Authorities are empowered to grant such permissions;

(e) if so, the names of the control release medicines for which different State Drug Authorities granted permissions during last two years alongwith composition of each;

(f) whether Government granted the permission of Venterline control release capsules;

(g) if so, the names of the authority who granted the permission with date;

(h) whether all studies, tests and trials were conducted before granting the permission; and

(i) if so, the details therof?

THE MINISTER OF HEALTH AND FAMILY WELFARE AND THE MINISTER OF CIVIL AVIATION (SHRI MOTI LAL VORA): (a) The requirements for obtaining permission for control release formulations include *invitro* dissolution studies, *in-vivo* blood level studies and/or the rapeutic trials and any co-relation that may exist between *in-vitro* and *in-vivo* studies.

(b) During the last two years the Drugs Controller (India) has not granted permission to market any new control release formulation.

(c) In view of (b) above, does not arise.

(d) The guidelines for Introduction of New Drugs includes control release preparation as "new" drug and as such the Drugs Controller (India) is the competent authority to grant permission to market control release formulations. However, the guidelines have not yet become a statutory and the State Drug Control Authorities in consultation with heir experts have been licensing formulations including control release preparation.

(e) to (i) The names of control release preparations that might have been licensed by different State. Drug Control authorities during the last two years are not available with the Central Government.

Reorientation of medical education

1892. SHRI HARVENDRA SINGH HANSPAL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the reorientation of medical education (Rome) scheme launched by the Central Government in 1977 has not been effectively implemented due to lack of response from the medicos;

(b) whether Government have since decided to transfer the scheme to the State's plan from the next Five Year Plan;

(c) whether the views of the State Governments have been considered in this regard; and